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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/030,606	02/25/1998	JIANGCHUN XU	210121.428C3	7583

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[REDACTED] EXAMINER

DAVIS, MINH TAM B

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1642

DATE MAILED: 11/05/2002

33

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/030,606	XU ET AL.
	Examiner	Art Unit
	MINH-TAM DAVIS	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 August 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23,24,29-36 and 41-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 23,24,35 and 36 is/are allowed.
- 6) Claim(s) 29-34, 41-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 23-24, 29-36, 41-46 are being examined.

Claims 23-24, 35-36 are free of prior art and are allowable

The following are the remaining rejections.

REJECTION UNDER 35 USC 101, UTILITY

Rejection under 35 USC 101 of claims 29-34, 41-46 pertaining to lack of a specific and substantial utility remains for reasons already of record in paper No.30.

Applicant argues that it is more likely than not than one could practice the claimed invention. Applicant argues that Applicant does not claim a method for distinguishing between localized and advanced for metastasized prostate carcinoma. Applicant asserts that as prostate specific markers are not detectable in serum of normal individuals, the identification of the presence of a prostate specific marker in the circulation of a patient is indicative of the presence of prostate cancer in the patient. This utility would be also useful for distinguishing between localized and advanced or metastasized prostate carcinoma. Applicant asserts that Gelmini et al supports the claim

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invention, because Gelmini et al teach that using a new polymerase chain reaction, 32% of peripheral blood samples from prostate cancer patients are positive, whereas no positive samples are found in the control, healthy subjects.

Applicant further asserts that the disclosure of Gelmini et al, Kibel et al and Ren et al, which teach that it is unpredictable that metastasized prostate cells still express the claimed sequence, because expression of a sequence could be lost during the progression toward metastasis, do not negate the recognition that Applicant's asserted utilities are more likely than not true. Applicant asserts that in some instances a protein may have altered expression in metastatic cancer versus primary cancer, however, this does not compromise the general contention set forth by Applicant that there would be a reasonable expectation that the claimed prostate-specific sequences are useful for the detection of cancer in a patient, in view of the specification, in view of the previously submitted Declaration by Dr. Houghton, and further in view of the general knowledge in this art.

Applicant's arguments set forth in paper No.32 have been considered but are not deemed to be persuasive for the following reasons:

It is noted that the specification, and the Declaration by Dr. Houghton only disclose that the claimed sequences are prostate specific. There is no disclosure or indication that the claimed sequences are detected in serum of prostate cancer patients and not in normal controls, or overexpressed in serum as compared to normal controls.

It is further noted that the claimed polynucleotides are organ specific, i.e. specific to prostate, and thus their utilities, based solely on prostate specific property, such as

treating or detecting prostate cancer are not specific, and are shared by other unrelated prostate specific molecules.

Applicant has argued that since the claimed sequences are prostate specific, detection of said sequence in the serum would indicate that the primary prostate cancer has become invasive and entered the circulation. However, it is unpredictable that one could detect the claimed sequences in serum of prostate cancer patients and not in normal controls, i.e. in invasive prostate cells that enter the circulation, because gene expression of primary and metastatic cells are different, wherein loss of expression of genes frequently occur during progression toward metastasis, as taught by Kibel et al and Ren et al. Further, although a single prostate specific gene, PSA, is detected in the serum of patients with prostate cancer, and not in normal controls, one could not extrapolate to any other prostate specific gene, because expression of different gene sequences are independent and unrelated to the expression of other gene sequences. In addition, MPEP 2164.08(a) teaches that a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claims because the specification disclosed at most only those means known to the inventor. *In re Hyatt*, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983). Thus based on a single disclosure by the art, Gelmini et al, on expression of a single prostate specific gene, PSA, one could not extrapolate to the expression of the claimed prostate specific sequences, and thus the claims would be non-enabled according to MPEP 2164.08(a).

Thus in view of the teaching of Kibel et al and Ren et al, and MPEP 2164.08(a), one could not predict that the claimed sequences would be useful for detecting primary prostate cancer cells that have become invasive and entered the circulation.

In view of the above, the claimed sequences lack specific and substantial utilities.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

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872-9306 for regular communications and 703-872-9307 for After Final
communications.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is 703-308-
0916.

MINH TAM DAVIS

October 30, 2002



MINH TAM DAVIS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1630